K140831

510(k) Summary

APR 15 2014

Submitter Information

A.	Company Name:	CareFusion
B.	Company Address:	10020 Pacific Mesa Blvd. San Diego, CA 92121
C.	Company Phone:	(858) 617-3042
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E.	Contact Person:	Larry Walker
F.	Date Summary Prepared:	March 20, 2014

Device Identification

A.	Trade Name	MaxZero Extension Sets with Needleless Connector
B.	Common Name:	IV Administration Sets
C.	Classification:	IV Administration Set, Needleless Connector, Closed Access, 21 CFR 880.5440, (Product code FPA)

Legally Marketed Predicate Device for Substantial Equivalence

Predicate Device	Manufacturer	510(k) #	Date Cleared
MZ1000 Needleless Connector	CareFusion	K132413	August 29, 2013
Medegen Pressure Rated Extension Sets	CareFusion (formerly Medegen)	K083472	December 9, 2008
Medegen Intravascular Administration Set and Extension Set	CareFusion (formerly Medegen)	K051499	June 22, 2005

Rational for Substantial Equivalence

The information provided in the premarket notification demonstrates that the subject CareFusion MaxZero Extension Set with Needleless Connector is substantially equivalent to the legally marketed predicated devices. The subject MaxZero Extension Sets with Needleless Connector and the predicate Medegen Extension Sets are intended to be used for the delivery and/or aspiration of fluids to/from an IV catheter in a hospital environment. The subject and the predicate devices are similar in physical properties, materials, and configuration. Each device includes connectors that allow for needleless access to the IV line during IV therapy eliminating the risk of needle injury. The subject device incorporates the predicate MZ1000 Needleless Connector bonded directly to IV tubing. Components of the subject devices are made of materials that are substantial equivalent to the predicate devices listed above and this submission includes comprehensive biocompatibility testing for all device materials included in this submission.

Device Description

The CareFusion MaxZero Extension Sets with Needleless Connector are intravascular extension sets intended for single patient use, including pediatrics and immunocompromised patients, for direct injection, intermittent infusion continuous infusion or aspiration of drugs, blood and fluids. All MaxZero Extension Sets with Needleless Connector include the previously cleared zero reflux MZ1000 Needleless Connector (K132413) bonded to the extension set tubing. The MZ1000 needleless connector allows thorough and easy disinfection due to a solid, flat smooth surface and eliminates the risk of needlestick injuries. The MaxZero Extension Sets with Needleless Connectors are sterile single patient devices that can be used for seven (7) days and 200 activations. All extension sets included in this submission are not made from natural rubber latex or DEHP.

The following model numbers are subject to this submission:

Model Number	Description	Tubing ID	Tubing OD
MZ5301	Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock [≈ 7" (18 cm); ≈ 0.40 ml]	0.042"	0.079"
MZ5302	Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock [≈ 7" (18 cm); ≈ 0.40 ml]	0.042"	0.079"
MZ5303	Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock [≈ 7" (18 cm); ≈ 0.50 ml]	0.060"	0.144"
MZ5304	Pressure rated extension set, MaxZero connector, slide clamp, spin male luer lock [≈ 7" (18 cm); ≈ 0.50 ml]	0.060"	0.144"
MZ5305	Pressure rated extension set, MaxZero connector, spin make luer lock [≈ 7" (18 cm); ≈ 0.50 ml]	0.060"	0.144"
MZ5306	Pressure rated extension set, minibore tubing, MaxZero connector, spin make luer lock. [≈ 7" (18 cm); ≈ 0.40 ml]	0.042"	0.079"
MZ5307	Bi-fuse pressure rated extension set, minibore tubing, (2) MaxZero connectors, (2) side clamps, spin male luer lock. [≈ 7" (18 cm); ≈ 0.80 ml]	0.042"	0.079"
MZ5308	Bi-fuse pressure rated extension set, (2) MaxZero connectors, (2) slide clamps, spin make luer lock. [≈ 6" (15 cm); ≈ 0.90 ml]	0.060"	0.144"
MZ9284	Bi-fuse extension set, (2) MaxZero connectors, (2) check valves (2) slide clamps, spin make luer lock [≈ 7" (18 cm); ≈ 0.90 ml]	0.042"	0.079"
MZ9285	Bi-fuse extension set, (2) MaxZero connectors, (2) slide clamps, spin make luer lock [≈ 7" (18 cm); ≈ 0.90 ml]	0.60"	0.144"

Intended Use

Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.

Non Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.

Substantial Equivalence Table

Device	CareFusion MaxZero Extension Sets with Needleless Connector	CareFusion (formerly Medegen) Pressure Rated Extension Sets	CareFusion (formerly Medegen) Intravascular Administration Set and Extension Set
510(k) #	TBD Subject device	K083472	K051499
Fluid contacting materials	Tubing- PVC Luer- Co-polyester Needleless Connector – Polycarbonate/silicone Male Spin lock – ABS thermoplastic Bifurcated Connecter- PVC	Tubing- PVC Luer- Co-polyester Check Valves- ABS thermoplastic Needleless Connector – Polycarbonate/silicone Male Spin lock – ABS thermoplastic Bifurcated Connecter- ABS	Tubing- PVC Luer- Co-polyester Check Valves- ABS thermoplastic Needleless Connector – Polycarbonate/silicone Male Spin lock – ABS thermoplastic Bifurcated Connecter- ABS
Needleless Connector	CareFusion MZ1000 (K132413)	CareFusion MaxPlus Tru-Swab Connector (K072542)	CareFusion NAC Plus Needleless Connector (K011193)
Functional Use	Direct Injection, intermittent infusion, continuous infusion, aspiration	Direct Injection, intermittent infusion, continuous infusion, aspiration	Direct Injection, intermittent infusion, continuous infusion, aspiration
Packaging	Tyvek/film pouch	Tyvek/film pouch	Tyvek/film pouch
Sterilization Method	E-Beam	E-Beam	Irradiation
Usable Life	7 days 200 activations	3 days 96 activations	Per CDC guidelines

Technical Characteristics

Technological Characteristics
Zero Reflux Needleless Connector
Designed to prevent microbial ingress
Needleless connector can be disinfected with 3 sec scrub with 70% IPA
Maximum clinical use of 7 days 200 activations (single patient use)
Non-hemolytic
Can be used with low power injectors with maximum of 325 psi & flow rate of 10ml/second (pressure rated sets)
Not made with DEHP
Safe for use in MRI environment
Not made with natural latex rubber
Sets can be used with harsh infusates

Clinical Data

There is no clinical data included in this submission.

Non-Clinical Data

CareFusion performed design verification performance testing to verify, demonstrate and support the claim of substantial equivalence to the predicate devices. All test results met their acceptance criteria and support that the MaxZero Extension Sets with Needleless Connector are appropriately designed for their intended use.

Testing performed included:

- Microbial ingress and barrier testing

- Hemolysis testing
- Shelf life performance testing
- Harsh Infusates testing
- ISO Testing
- Priming volume/flow rate testing
- Biocompatibility testing to applicable section of ISO 10993
- Sterilization validation testing

A complete list of functional/performance testing protocols and reports are included in Section 18 of this submission.

Conclusion

The results of the non-clinical testing exhibited that no new issues of safety and efficacy are raised with the proposed introduction of the MaxZero Extension Sets with Needleless Connector. The device met the acceptance criteria for all functional, microbial ingress, sterility, biocompatibility and other performance criteria, which verify it to be substantially equivalent to the predicate devices. The conclusion drawn from the performance testing demonstrate that the MaxZero Extension Set with Needleless Connector is as safe as effective and performs at least as safe and effectively as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2014

CareFusion
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo MN 55313

Re: K140831
Trade/Device Name: MaxZero Extension Sets with Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: March 27, 2014
Received: April 4, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

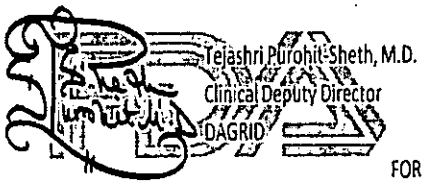
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140831

Device Name
MaxZero Extension Set with Needleless Connector

Indications for Use *(Describe)*

Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration. This set may be used with power injector procedures to a maximum pressure of 325 psi at a flow rate of 10mL per second.

Non Pressure Rated: The MaxZero multi fuse extension set with needleless connector(s) is for single use only. The extension set may be used for direct injection, intermittent infusion, continuous infusion or aspiration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

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